

## SPECIALTY GUIDELINE MANAGEMENT

### SKYCLARYS (omaveloxolone)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### FDA-Approved Indication

Skyclarys is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for initial requests:

- A. Testing or analysis confirming a mutation of the *FXN* gene
- B. Chart notes or medical record documentation confirming the member demonstrates clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling)

##### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a physician who specializes in the treatment of Friedreich's ataxia or a neurologist.

##### IV. CRITERIA FOR INITIAL APPROVAL

###### **Friedreich's ataxia**

Authorization of 12 months may be granted for treatment of Friedreich's ataxia when all of the following criteria are met:

- A. The diagnosis is confirmed by detection of a mutation of the *FXN* gene.
- B. Member exhibits clinical manifestations of disease (e.g., muscle weakness, decline in coordination, frequent falling).
- C. Member is 16 years of age or older.

##### V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV who are experiencing benefit from therapy as evidenced by disease stability

Reference number(s)
5803-A

or disease improvement (e.g., improvement in speech or swallowing, upper/lower limb coordination, upright stability).

## VI. REFERENCES

1. Skyclarys [package insert]. Cambridge, MA: Reata Pharmaceuticals, Inc.; January 2024.
2. Friedreich's ataxia: NORD. National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/friedreichs-ataxia/>. Last updated October 24, 2023. Accessed March 15, 2024.